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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,423	06/28/2001	Ronald H. Chiarello	SYNGEN-06067	6875

23535 7590 06/17/2003

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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

8

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/894,423	CHIARELLO ET AL.
	Examiner Celine X Qian	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 07 April 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1,3 and 4 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,3 and 4 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 6/28/2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

Claims 1, 3 and 4 are pending in the application. Claim 2 is cancelled.

This Office Action is in response to the Amendment filed on 4/7/03.

### ***Response to Amendment***

The objection to the specification has been withdrawn in light of Applicants' amendment.

The rejection of claims 2 and 3 under 35 U.S.C. 112 2<sup>nd</sup> paragraph is moot in light of Applicants' cancellation of the claims.

The rejection of claims 1, 3 and 4 under 35 U.S.C.102 (b), (e) has been withdrawn in light of Applicants' amendment of the claims.

The objection of drawing is maintained for reasons set forth of the record mailed on 9/30/02 and further discussed below.

The rejection of claims 1, 3 and 4 under 35 U.S.C.103 (a) is maintained for reasons set forth of the record mailed on 9/30/02 and further discussed below.

### ***Response to Arguments***

#### ***Drawing Objection***

In response to the drawing objection, Applicants state that the Figures 1A, 1B, 2A and 2B are not known in prior art, but represent embodiments of Applicants' novel chemistries in various reactions associated with methods for labeling oligonucleotides. Therefore, they should not be labeled as prior art in the legend.

Applicants' argument has been fully considered, but this statement appears to be contradictory to the disclosure in the specification. For example, the specification discloses "currently available technologies for the attachment of 5' end labels to synthetic oligonucleotides

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rely on two general approaches. The most popular approach... This process is exemplified in Figures 1A and 1B" (see page 11, lines 9-14) and "a two step variation of this approach is used only in cases where the corresponding phosphoramidite is not available. This approach is exemplified in Figures 2A and 2B..."(see page 12, lines 3-14) Such disclosure indicates that the reactions exemplified in 1A, 1B, 2A and 2B are known in the art at the time the application is filed. Therefore, the objection is maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snitman et al., in view of Vinayak et al.

In response to the rejection, Applicants argue that the Examiner does not give a reason to combine the references. Applicants argue that the references do not teach the advantages offered by the specific bifunctional linker arms in the claimed method, therefore, the invention is not obvious.

Applicant's arguments have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally

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available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine the reference is based the knowledge gained from the combined teaching of Snitman and Vinayak et al. Snitman et al. teach a phosphoramidite linker with the formula  $[(CH_3)_2CH]_2NP(OCH_3)O(CH_2)_8NH(DMT)$ , which only differs from the claimed linker for having methyl moiety on the phosphate oxygen instead of cyanoethyl moiety. Vinayak et al. also teach a phosphoramidite linker (col. 11, structure 8 when R is cyanoethyl) with very similar structure to the claimed linker (especially the first one) except it has only one methoxy moiety. Based on the reaction chemistry disclosed in the references, it would have been obvious to one of ordinary skill in the art that variation such as one methoxy group instead of two, or having methyl instead of cyanoethyl at that position does not affect the ability for the linker's function as long as it can undergo beta-elimination. In addition, the alleged advantages offered by the claimed bifunctional linker arms are not a limitation of the claims. Therefore, the claimed invention is *prima facie* obvious to one of ordinary skill of the art at the time the invention was made.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.  
June 11, 2003

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER